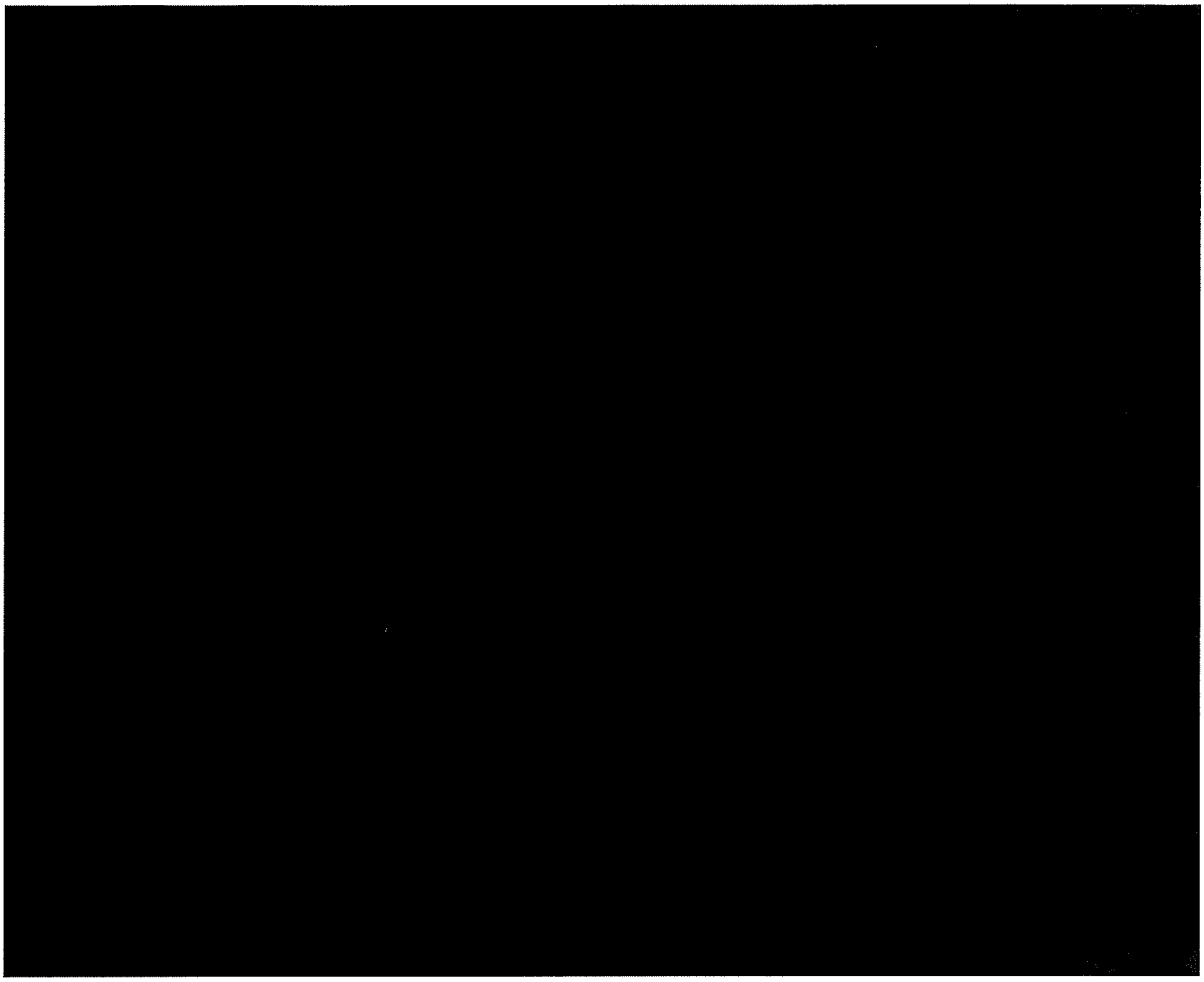
EXHIBIT F



From: saugustine@augbiomed.com
To: kmclinch@comcast.net
Cc:
Sent: 2017-03-02 8:47:32 PM
Subject: 3M recalls Bair Hugger from orthopedics

Re: 3M recalls Bair Hugger from orthopedics

Hi Kathy,

I hope all is well. In light of all of the misinformation from 3M about Bair Hugger® vs. HotDog, I thought you might be interested in 3M's latest actions—which definitely speak louder than words.

Facing more than 1,400 federal-court lawsuits claiming that Bair Hugger® forced-air warming causes catastrophic orthopedic infections, 3M is quietly replacing it with their own electric mattress. *Is this substitution a "recall" or just clever marketing?*

3M would like you to believe that this is merely an "enhancement" or a "substitution" -- call it anything other than a "recall." Why? Because a "recall" signals a business catastrophe, especially during mass tort litigation. A recall ordered by the FDA is a government *proclamation* that a product is not safe. A recall initiated by the company is an *admission* that a product is not safe. A recall during mass tort litigation is in essence a

guilty plea.

Clearly this is a "recall" as defined by the FDA.[1,2] Using the language of the FDA , Bair Hugger is "adulterated" and the removal of an adulterated device from the market is by definition, a "recall." It is axiomatic that adulterated devices violate FDA regulations, especially when the adulteration results in a significant safety risk.

The FDA statutes are very precise: recalls must be publicly announced, with notification of the products' safety risks given to both the FDA and to the customers. In my opinion, 3M's sneaky "silent recall" is clearly unlawful. In essence, they are asking their customers to help them violate the law.

This silent Bair Hugger recall is a direct contradiction of the *false assurances of safety* that 3M has repeatedly made over the past six years. How many of your patients have been put at risk of devastating implant infections based on 3M's false assurances of safety?

Apparently, simply lying to its customers is no longer sufficient. We have now observed that, when orthopedic surgeons refuse to allow Bair Hugger in their ORs, 3M quietly replaces it with their electric mattress.

If your vendor will openly lie to you about safety, putting your patients at significant risk of catastrophic infections simply to protect their profits, are they worthy of being your partner? Are they worthy of your trust? Are they worthy of your business? Business ethics cannot be optional when patients' lives are at stake.

I hope that you will consider HotDog® warming when you replace Bair Hugger in orthopedics. HotDog is air-free and waste heat-free, much safer, nearly twice as effective and much less expensive. Most importantly, you can trust Augustine Temperature Management to put patients ahead of profit.

Please give me a call or email if you have questions, comments or would like to discuss this matter further. Please feel free to forward this email to your colleagues.

Warm regards,

Scott

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1. A recall is any correction or removal of a device which is intended to resolve a failure to meet specifications or perform as intended--in other words, is "adulterated."

> "FDA generally considers devices that fail to meet represented specifications or that fail to perform as represented to be of a quality below that which they purport or are represented to possess, rendering them adulterated under section 501(c) of the FD&C Act [21 U.S.C. 351(c)]. Changes intended to resolve a failure to meet specifications or failure of the device to perform as represented would generally constitute recalls." (FDA Guidance Document: Distinguishing Medical Device Recalls from Medical Device Enhancements, October 15, 2014)

http://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm418469.pdf

2. Bair Hugger is "adulterated," which means that it does not comply with the specifications that were submitted by the company to the FDA in order to get 510k clearance for selling the product.

Ÿ 3M falsely claimed that Bair Hugger blankets "…feature a tape barrier which prevent air from migrating toward the surgical site." This statement is false because it was later discovered that the waste FAW heat and air escape from under the surgical table near the floor. The contaminated warm air then rises alongside the table, outside the surgical drape, and has been shown in many published studies to contaminate the sterile surgical field. *The tape on the blanket offers no protection from this contamination whatsoever.*

Ÿ 3M falsely claimed that Bair Hugger blowers have HEPA filters (99.97% efficiency) later amended to 93% efficiency. *This statement is false because, in fact, Bair Hugger filters were later reduced to only 63% efficiency. As* a result, nearly every Bair Hugger blower is internally contaminated with bacterial colonies that are then aerosolized into the high velocity air passing through the unit.

Ÿ 3M claimed that: "Two studies have concluded that the Bair Hugger® 500 Series Units do not increase the incidence of microbial or wound contamination." This was a true statement in 2000 but the two studies referenced were exceptionally weak from a scientific point of view and poorly designed to answer the specific question at hand. 8-10 years later it was shown with the publication of seven much more scientifically robust studies, that this statement was in fact false. 3M has continued to promote its unsupported story of safety despite the overwhelming evidence to the contrary provided by the more recent research.

[redacted]

3M's "Silent" Recall of Bair Hugger?

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Dr. Haught,

3M's "Silent" Recall of Bair Hugger?

Facing more than 1,300 federal-court claims that Bair Hugger® forced-air warming causes catastrophic orthopedic infections, 3M is quietly replacing Bair Hugger with an alternative device.

Is this substitution a recall?

"3M may deny that this is a recall," says Dr. Scott Augustine, inventor of both Bair Hugger and air-free HotDog electrical warming," but clearly it is an admission of a problem. 3M has a statutory obligation to publicly report their Bair Hugger safety problem, not to secretly pull the product from the market. FDA regulations are very clear on this point."

In federal Multi-District Litigation, plaintiffs claim multiple FDA violations, that, if true, could require a recall. Bair Hugger, they claim, is clearly "adulterated," meaning that it does not perform as claimed in the 510k. Plaintiffs claim that 3M did not accurately describe what happens to the Bair Hugger waste heat or the poor quality of filtration. Adulterated devices violate FDA regulations, especially when the adulteration results in a significant safety risk.

For years, Dr. Augustine has been warning of the unintended consequence of airborne contamination with Bair Hugger, particularly in orthopedic surgery. 3M has attacked air-free warming and assured customers that Bair Hugger is safe. Now that orthopedic surgeons are concerned, contends Dr. Augustine, 3M is substituting its own electric mattress.

"To make it worse, warming with just a mattress is inadequate because it doesn't cover enough surface area. Patients will still be cold," says Dr. Augustine.

Dr. Augustine's latest invention, air-free HotDog® patient warming, is a reusable electric blanket AND mattress warming system that does not blow air.

According to FDA Guidance:

"a recall can be any correction or removal of a device that has been distributed when the device is in violation of ...FDA regulations and the violation is one against which the FDA would initiate legal action."

Distinguishing Medical Device Recalls from Medical Device Enhancements, citing to Federal Food, Drug, and Cosmetic Act (FD&C Act) [21 U.S.C. 360h]Federal Food, Drug, and Cosmetic Act (FD&C Act) [21 U.S.C. 360h]
http://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm418469.pdf

About Orthopedic Infection Advisory

Orthopedic Infection Advisory (OIA) is dedicated to educating healthcare professionals about the risks and consequences of orthopedic infections. OIA monitors scientific publications for research relating to such infections, with particularly emphasis on peri-prosthetic infections. OIA is supported by Augustine Temperature Management.